

**Notice of Allowability**

Application No.

09/580,523

Applicant(s)

ZHOU, XIAO-MAI

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to interview of 07/07/06 & 07/13/06.
2. ☒ The allowed claim(s) is/are 109-124, renumbered as 1-16.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 05/03/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 07/07/06 & 07/13/06
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### EXAMINER'S AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/29/06 has been entered.
2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with SUSAN MACK on 07/13/06.

The application has been amended as follows:

Claim 109 was amended as follows:

"at least" on the first line of claim 109 was deleted.

Claim 114 was amended as follows:

"at least" on the first line of claim 114 was deleted.

3. The following is an examiner's statement of reasons for allowance:

The mutation at Serine 118 of the human BAD polypeptide SEQ ID NO:1, by replacement with Alanine 118 or Glycine 118, wherein said mutation inhibits phosphorylation at Serine 118, and promotes *in vitro* cell death, is novel. The closest prior art US 5,965,703 (of record) does not teach mutation of the human or mouse BAD polypeptide. US 5,965,703 only

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discloses: 1) the wild type human BAD polypeptide SEQ ID NO:3, which is the same as the wild type, non-mutated SEQ ID NO:1 of the claimed invention, and 2) the mouse BAD polypeptide SEQ ID NO:3, which is 75% similar to SEQ ID NO:1 of the claimed invention (see Office action of 02/10/05 and 08/25/05).

Support for a mutant BAD having “at least 85%, 90% or 95% sequence identity” with SEQ ID NO:1, and “comprising amino acids 103-123 of SEQ ID NO:1” of the new claims 109-113, is found on page 12, second paragraph, page 45, last paragraph, and page 46, first paragraph of the instant application. The amino acid sequence consisting of amino acids 103-123 of SEQ ID NO:1 is a fragment of the BH3 domain of the human BAD polypeptide SEQ ID NO:1. The unphosphorylated sequence consisting of amino acids 103-123 of SEQ ID NO:1 by itself would be sufficient to promote apoptosis, in view of the teaching of Moreau et al, 2003 (JBC, 278 (21): 19426-19435) that the human BAD domain consisting of only amino acids 108-123 of the human BAD BH3 domain by itself is sufficient to promote apoptosis, by its binding to Bcl-XL (see also Applicant response of 05/26/06, on page 7).

Support for a mutant BAD having “at least 85%, 90% or 95% sequence identity” with SEQ ID NO:1, and “comprising amino acids 106-132” of SEQ ID NO:1 of the new claims 114-118, is found on page 9, second paragraph, especially lines 9-14, page 41, sequence alignment, p.43, second paragraph, page 45, last paragraph, page 46, first paragraph, and page 67, second paragraph, and last paragraph, bridging page 77, and figure 3B of the instant application. The amino acid sequence consisting of amino acids 106-132 of SEQ ID NO:1 is the BH3 domain of the human BAD polypeptide SEQ ID NO:1, as shown by sequence alignment with the BH3 domain consisting of amino acids 143-168 of the murine BAD polypeptide SEQ ID NO:2. The

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unphosphorylated BH3 domain of the mouse BAD polypeptide by itself is sufficient to promote apoptosis, by its binding to Bcl-XL.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH-TAM DAVIS  
July 14/06

  
JEFFREY SIEW  
SUPERVISORY PATENT EXAMINER